

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN,
LOSARTAN, AND IRBESARTAN
PRODUCTS LIABILITY
LITIGATION

MDL No. 2875

THIS DOCUMENT RELATES TO ALL
CASES

HON. ROBERT B. KUGLER
CIVIL NO. 19-2875 (RBK)(KMW)

**PLAINTIFFS' MOTION TO STRIKE
DEFENDANTS' EXPERT MICHAEL B. BOTTOREFF'S
NEW AND ALTERED GENERAL CAUSATION OPINIONS**

Plaintiffs respectfully move the Court to strike the new and altered opinions of Defendants' expert Dr. Michael Bottorff. Dr. Bottorff offered new and altered general causation opinions in his January 12, 2022, class certification expert report. Such new expert general causation opinions are in contravention of CMO 23 and would be highly prejudicial to Plaintiffs. Therefore, this Court should strike the opinions described herein.

BACKGROUND

Case Management Order No. 23 ([ECF 863](#)) specifies that the deadline for Defendants to have served their expert reports addressing general causation was on August 2, 2021. Plaintiffs and Defendants both agreed during a February 2022 case management conference that the general causation phase of expert reports had passed:

[Mr. Slater:] Because as Your Honor knows, **the general causation phase of expert reports is long over**. Those reports were exchanged, the depositions were taken, and the briefs were filed, and the hearings are imminent, next month.

These experts, some of them have new general causation opinions, new analyses of general causation concepts and opinions. Some of these experts were general

causation experts in the first round and they're now finding and changing and adding to those opinions, et cetera.

So as the defense said, they expect that we're going to take no testimony from these witnesses on general causation at this stage. And frankly, we agree, because as part of the briefing when them time comes, we intend to ask the Court to strike anything in these reports that is a general causation opinion because that was supposed to be done in the general causation phase.

[Ms. Lockard:] And we have now provided additional expert reports, supplements, that address the issues raised by plaintiffs' class certification expert. So the new reports are limited to class certification issues or to rebut and address issues and opinions that were presented in plaintiffs' class certification expert reports.

So we don't agree that they are expanding their general causation opinions. That phase of the case is done. You know, we would not attempt to work additional opinions in there. I think their prior testimony on that is complete. So we certainly don't want to open them up to extended depositions where they can get into rehashing of the general cause opinions.

(Ex. A, 2/2/2022 CMC Tr. 13:7-23; 14:16-15:2 (emphasis added)).

Per CMO 23, Defendants served Dr. Bottorff's general causation expert report on August 2, 2021. ([ECF 1712-5](#), Bottorff General Causation Report). On January 12, 2022, Defendants served Dr. Bottorff's expert report addressing class certification. (Ex. B, Bottorff Class Cert. Report). While Dr. Bottorff does not remember making changes to his previous report, several additions and changes were made to his general causation opinions. (Ex. C, Bottorff 3/25/22 Depo Tr. 10:4-6, 18:21-19:2, 20:21-21:6, 22:10-23:23). Upon being confronted with the changes and additions to his general causation opinions, Dr. Bottorff testified, "I - - I sat down and wrote it de novo with the same knowledge base and information." (Ex. C, Bottorff Depo Tr. 21:21-23).

A. New and Altered General Causation Opinions on NDMA/NDEA Bioavailability

Following *Daubert* hearings, Dr. Bottorff is the only defense general causation expert that the Court permitted to opine on the bioavailability of NDMA/NDEA. Dr. Bottorff's class certification expert report contains a significant change and addition to Dr. Bottorff's general causation opinion related to the bioavailability of NDMA/NDEA.

In Dr. Bottorff's general causation report he opined that NDMA/NDEA in "[s]maller oral doses are metabolized in the liver almost completely, **minimizing** exposure to other tissues and organs." ([ECF 1712-5](#), Bottorff General Causation Report 28:485-486). This sentence was changed in Dr. Bottorff's class certification report to read, "Oral doses at the levels detected in the generic valsartan at issue in this litigation are metabolized in the liver almost completely, **preventing** exposure to other tissues and organs." (Ex. B, Bottorff Class Cert. Report 48:761-762; Ex. C, Bottorff Depo Tr. 19:15-22:3). Altering Dr. Bottorff's opinion from the liver being able to **minimize** NDMA/NDEA exposure to other tissues and organs, to the liver being able to **prevent** NDMA/NDEA exposure to other tissues and organs is a significant material change to Dr. Bottorff's general causation opinion. As such, Plaintiffs request that Dr. Bottorff's opinion that the liver can **prevent** NDMA/NDEA exposure to other tissues and organs be struck, and that Dr. Bottorff be precluded from offering such opinion at trial.

Dr. Bottorff's class certification report also included the general causation opinion that "NDMA/NDEA in valsartan will not reach systemic circulation", which was absent in Dr. Bottorff's general causation report. (*Cf.* Ex. B, Bottorff Class Cert. Report 47:749 with [ECF 1712-5](#), Bottorff General Causation Report 27; Ex. C, Bottorff Depo Tr. 16:1-17:4). Plaintiffs request that Dr. Bottorff's opinion that "NDMA/NDEA in valsartan will not reach systemic circulation" be struck, and that Dr. Bottorff be precluded from offering such opinion at trial.

B. New General Causation Opinion on Human DNA Repair Mechanisms

Finally, the general causation opinion that "DNA repair mechanisms in humans can be as much as 10x higher than rats, indicating a more active DNA repair in humans compared to rats" was added to Dr. Bottorff's class action report. (*Cf.* Ex. B, Bottorff Class Cert. Report 52:830-831

with [ECF 1712-5](#), Bottorff General Causation Report 62). Dr. Bottorff confirmed in deposition that this opinion did not appear in his general causation expert report:

Q: All right. Dr. Bottorff, now that you've had time to review your general causation expert report, did you find anywhere within that report that you gave the opinion that DNA repair mechanisms in humans can be as much as ten times higher than rats?

A: No, I - - I didn't find it.

(Ex. C, Bottorff Depo Tr. 23:17-23). Plaintiffs request that Dr. Bottorff's new general causation opinion that "DNA repair mechanisms in humans can be as much as 10x higher than rats, indicating a more active DNA repair in humans compared to rats" be struck, and that Dr. Bottorff be precluded from offering such opinion at trial.

CONCLUSION

For the reasons set forth above, Plaintiffs respectfully request that the Court strike Dr. Bottorff's new and altered general causation opinions and preclude Dr. Bottorff from offering such opinions at trial.

Dated: May 3, 2022

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 3rd day of May 2022, I caused a true and correct copy of the foregoing to be filed and served upon all counsel of record by operation of the Court's CM/ECF system. In addition, I certify that unredacted copies of foregoing document will be served contemporaneous to filing via email on the Court, Special Master, and the Defense Executive Committee at DECValsartan@btlaw.com.

/s/ C. Brett Vaughn
C. Brett Vaughn